

- Group I. Claims 1-15, drawn to a method of performing *ex-vivo* expansion of a gene modified hematopoietic stem cell, encoding an ABC transporter.
- Group II. Claims 14-21, drawn to a method of engrafting a mammal with a gene modified hematopoietic stem cells encoding an ABC transporter.
- Group III. Claims 22-26, drawn to a method of identifying a stem cell wherein detection is performed with an antibody that binds to BCRP.
- Group IV. Claims 27-28, drawn to a method of diagnosing acute myelogenous leukemia (AML) by determining the expression of BCRP in a leukemic cell.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group I, with traverse, Claims 1-15, which are drawn to a method of performing *ex-vivo* expansion of a gene modified hematopoietic stem cell, encoding an ABC transporter.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claims 14-21 of Group II are drawn to a method of engrafting a mammal with a gene modified hematopoietic stem cells encoding an ABC transporter that are fundamentally related to Claims 1-15 of Group I, drawn to a method of performing *ex-vivo* expansion of a gene modified hematopoietic stem cell, encoding an ABC transporter. The search for any of the methods separately classified by the Examiner as the invention of Group II would require an additional search of the identical classes wherein the methods and compositions of Group I are classified, thus resulting in a duplicate search for the same material. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Group II with Group I can be made without serious burden, and therefore the Examiner must examine all of the claims of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group I and Group II is in order.

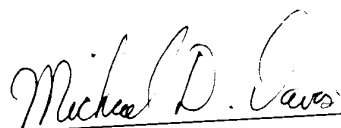
No fees are believed to be necessitated by the foregoing Response. However,

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should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,



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